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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,620	01/29/2007	Maria Sitges Berrondo	251989	9639

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EXAMINER
CARTER, KENDRA D

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
01/06/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,620	SITGES BERRONDO ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3 and 4* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3 and 4* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of November 11, 2011 made to the office action filed May 12, 2011. Claims 1, 3 and 4 are pending and amended. Claims 5-8 are cancelled.

In light of the claim amendments all previous rejections are withdrawn and new rejections are applied below. Since Applicant's amendments are about the withdrawn rejections, the Examiner will not respond other than in the new rejections based on the amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nekrassov et al. (Brain Research, 2000, vol. 868, pp. 222-229) in view of Dutov et al. (Zh nevropatol Psikhiatr Im SS Korsakova, 1986, vol. 86, no. 6, pp. 850-855, translated to English), Woolf et al. (Antimicrobial Agents and Chemotherapy, June 1988, pp. 865-872) and Applicant's admitted art (see specification, page 3, paragraph 9).

Nekrassov et al. teach vinpocetine protects from aminoglycoside antibiotic-induced hearing loss in guinea pig in vivo (see title). Amikacin, the aminoglycoside antibiotic, increases the auditory brainstem response (ABR) at 4 and 8 kHz, but when vinpocetine is administered by i.p. at 2 mg/kg for 13 days after administration of Amikacin, the increase ABR threshold and latency is reduced (see abstract and page 225, section 3.5; addresses claims 1-3) in the first and later waves (i.e. P1, P3 and P4 in fig. 1; addresses claim 2).

Nekrassov et al. do not teach that the hearing loss is caused by epilepsy (claim 1); epileptic seizures are treated simultaneously (claim 1), nor that the treatment of the epileptic seizures are characterized by inhibiting epileptic cortical activity for ictal and post-ictal periods (claim 4). Nekrassov et al. also does not teach that the patient is pre-administered vinpocetine (claim 1).

Dutov et al. teach that Cavinton (i.e vinpocetine) treats epileptic seizures (see page 3 in whole of the translation).

Woolf et al. teach that ganciclovir administered 1 day before inoculation of cytomegalovirus labyrinthitis protect the cochlea from the histopathologic changes and hearing loss normally associated with cytomegalovirus labyrinthitis (see abstract).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the teachings of Nekrassov et al. and to treat epileptic seizures and hearing loss that is associated with epilepsy (claim 1) because of the following teachings: 1) Nekrassov et al. teach the treatment of hearing loss at 4 and 8 kHz with the Applicant's claimed compound; and 2) Dutov et al. teach that vinpocetine treats epileptic seizures (see page 3 in whole of the translation). Thus, regardless of the cause, hearing loss is still treated. One would be motivated to try a treatment for hearing loss regardless of its cause, especially if the hearing loss was treated. Further, since vinpocetine treats epileptic seizures, when the drug is administered it will also

treat the hearing loss (i.e simultaneous treatment of hearing loss caused by epileptic and epileptic seizures).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the teachings of Nekrassov et al. and treatment wherein the patient was pre-administered vinpocetine because of the following teachings: 1) Nekrassov et al. teach the treatment and prevention of hearing loss at 4 and 8 kHz with the Applicant's claimed compound; 2) Woolf et al. teach that prophylactic administration of ganciclovir protect the cochlea from the histopathologic changes and hearing loss normally associated with cytomegalovirus labyrinthitis (see abstract). Although the teaching of Woolf et al. is for a viral infection, Woolf et al. provides evidence that prophylactic administration of a drug to protect against hearing loss is known. Since it is known in the art that antiepileptic drugs result in hearing decline (see Applicant's specification page 3, paragraph 9), one skilled in the art would be motivated to try prophylactic administration of vinpocetine to reduce hearing loss and treat epileptic seizures.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the teachings of Nekrassov et al. and wherein the treatment of the epileptic seizures is characterized by inhibiting epileptic cortical activity for ictal and post-ictal periods because the Dotov et al. teach that epileptic seizures are treated. Thus, since the same drug is administered for the same purpose it would be

obvious that it would have the same mechanism inside the body once administered. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kendra D Carter
Examiner, Art Unit 1627

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627